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STATE OF NEVADA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH CARE FINANCING AND POLICY
NEVADA MEDICAID

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DRUG USE REVIEW (DUR) BOARD

Meadow Wood Courtyard
5851 S. Virginia St.
Reno, NV

Approved
Meeting Minutes
July 17, 2008

Committee Members Present:
David England, Pharm.D., Chairman
Paul Oesterman, Pharm.D.
Steven Parker, M.D.
Marjorie Uhalde, M.D.

Absent:
Keith Macdonald, R.Ph.
Steven Rubin, M.D.

Others Present:
Coleen Lawrence-DHCFP, Mary Griffith-DHCFP, Darrell Faircloth-DAG, Jeff Monaghan-FHSC, Dave Wuest-FHSC, Shirley Hunting-FHSC, Gosia Sylwestrzata-FHSC, Mike Steelman-Pfizer, Sandy Sierawski-Pfizer, John Stockman-Genentech, Craig Boody-Lilly, Doug Powell-Forest, Dan Bay-Abbott.

I. Call to Order and Roll Call

Chairman England called the meeting to order at 1:05 p.m.

II. Discussion and Approval of April 10, 2008 Minutes.

MOTION: **Paul Oesterman motioned to accept the minutes as presented.**
SECOND: **Marjorie Uhalde**
VOTES: **Unanimous**
MOTION CARRIED

III. Proposal by First Health Services on the Revision of the Prior Authorization Process for Patients Prescribed Gastrointestinal Agents

Jeff Monaghan reminded the Board that this item was discussed at the last meeting. The Board requested a "cleaned up" copy of the proposed criteria be presented at this meeting for discussion and action.

Dave Wuest distributed the current criteria which includes requirements such as lifestyle modification documentation, endoscopy, etc. The existing criteria treated most of the disease states as an acute condition when in fact they are chronic conditions. Based on input from pharmacists and physicians, it was felt the existing criteria should be revisited. He presented the proposed criteria which has been modified and streamlined as follows:

Section A.1.:
a. Gastric Esophageal Reflux Disease (GERD)
b. Duodenal/Peptic/Gastric/Gastrojejunal Ulcer Disease
c. Hypersecretory Conditions (Barrett's Esophagus, Zollinger-Ellison, etc.)
d. GI Hemorrhage
Approval will be given for the above:

-if the ICD-9 code for the disease state is documented on the prescription. The pharmacy will be required to enter the ICD-9 into the system and the claim will process without obtaining a prior authorization (PA), or
-the physician can follow the prior authorization process by completing a prior authorization form documenting a diagnosis of the disease.

Mr. Wuest stated that when the pharmacist enters the ICD-9 code, the prescription will process and any subsequent prescriptions with the same ICD-9 code will also go through. Traditionally, there has been a 30 day, 90 day or year limit applied to PAs that have been approved. A time limitation will not apply to claims entered with the ICD-9.

Dave England stated that the ICD-9 code seems to circumvent the review process. Can a review be accomplished without utilizing the PA paper process?

Mr. Wuest responded that retrospective review will be part of the process and reported to the Board. He added that though the PA approval rate for this class is very high, utilization has remained flat over last twelve months.

Ms. Lawrence said that by including the ICD-9 code on the prescription, we are accepting the physician's judgment that criteria have been met and the PA process will be bypassed. The restrictions were placed on this class initially due to high utilization and cost. The trend is now flat which also supports modifying the criteria.

Paul Oesterman stated that he supports the new criteria. At the last meeting, there was public comment about the concern for the hospital discharge on a Friday. The ICD-9 code will now eliminate that as an issue.

Mr. Wuest continued review of the proposed criteria.
Section A.1.:

e. Other Disease States Requiring a Prior Authorization
    1. Healing or maintenance of erosive esophagitis
    2. Prevention of NSAID induced gastric ulcers when receiving continuous treatment with NSAID therapy and the recipient is over the age of 60 or has a documented history of gastric ulcers.

Mr. Wuest stated that the ICD-9 codes for a. through d. are very clear and particular codes or range of ICD-9s that apply. The range for e.1. is very broad and confusing therefore the recommendation is to require the normal PA process. If the PA request form states the patient is being treated or maintained for this disease state, the PA will be approved. Length of approval will be for one year.

e.2. is a newer indication for treatment. It's a standard of care for these diseases that the patient should be on a PPI. Mr. Wuest stated that the system can be set up to allow the claim to process without a PA if there is claims history that the recipient is on an NSAID and is over 60 years of age. PA will be required if there is no claims history or if the recipient is under the age of 60.

PPI utilization will be tracked and reported to the Board. Length of approval for all PPIs approved through the Call Center will be for one year.

Jeff Monaghan stated that based on the revised criteria proposed, it is recommended that the generic PA form be used versus the current PPI PA form.

Public Comment

No comment.

Discussion and Action by Board Concerning Revisions to Clinical Prior Authorization Criteria for Gastrointestinal Agents

MOTION: **Paul Oesterman motioned to accept the proposed criteria for Proton Pump Inhibitors as presented.**
SECOND: **Steven Parker**
VOTES: **Unanimous**
MOTION CARRIED

IV. Proposal by First Health Services to Revise the Current Clinical Prior Authorization Criteria for Actiq® and Fentora® per Recent FDA Warning Updates

Jeff Monaghan stated that this issue was addressed two years ago. Consideration was given to restrict use to the FDA indication, but there was a concern that this approach would be too restrictive. He presented the current PA criteria which were approved at that time. Since that time, the warnings from the FDA and the literature have increased.

Fentora® is a fentanyl citrate buccal tablet. Actiq® is fentanyl citrate in the form of an oral transmucosal lozenge. Both deliver fentanyl citrate. There are minor differences in the PA criteria that are being proposed but both are the same drug with a different delivery system. The black box warnings for both Fentora® and Actiq® are very similar. Most of the more stringent warnings were related to Fentora®. Cephalon, the manufacturer of both products, sent out a letter to physicians in February, 2008, stressing the safety issues surrounding Fentora®. The major issue with fentanyl citrate is use in non-opioid tolerant patients. That's where many of the deaths have occurred. It's also being used for pain that it's not appropriate for. FHSC contacted several pain management specialists including Jim Marx, who sits on the Controlled Substance Task Force, is board certified in anesthesiology and addiction medicine. Dr. Marx said that the FDA indications are very strong and should be followed but the stronger argument is that there is no real reason to be using these medications except in very rare circumstances because of the safety issues and the abuse and diversion potential. Mr. Monaghan said that this drug is listed on the DEA's website as one of the most abused and diverted drugs in the state. He presented proposed criteria that fall in line with the FDA recommendations and boxed warnings. The proposed criteria are more specific in terms of the types of patients; opioid tolerance is defined. Approval is restricted to the FDA indication of malignant cancer pain which would not allow the drug to be available for migraines, headaches, fibromyalgia, etc., which the manufacturer also states it should not be used for.

Public Comment

No comment.

Discussion and Action by Board Concerning Revisions to Clinical Prior Authorization Criteria for Actiq® and Fentora®

Mr. Oesterman asked if the ICD-9 code for a malignant diagnosis could be utilized. Mr. Monaghan replied that using the ICD-9 will not allow the enforcement of the age and opioid tolerance criteria. Ms. Lawrence suggested that for the initial fill a PA would be required and on the next fill, if there is claims history after the effective date of the new criteria, the claim will process within the approval period without going through the PA process.

Mr. Monaghan stated that there will be several patients that will be moved off this medication that are currently on it. In the discussion with Dr. Marx, he felt 30-60 days is reasonable to help transition these patients. Guidelines for transitioning can be included.

Dr. Parker asked if it's known who is currently taking these medications. Dave Wuest stated that during the period 7/1/07 to 6/30/08, 46 recipients received the medication. A review of the diagnoses on the medical claims of 40 of the recipients indicated that 5 had a cancer diagnosis and 35 did not have a cancer diagnosis.

Dr. Parker felt a notification should be sent regarding the change in policy. Ms. Lawrence stated that the new criteria will take a minimum of forty days to be presented at a public hearing and an additional twenty days to implement. She felt because there are only 41 physicians, a letter could be sent and notification posted on the website as well.

Mr. England felt that the letter should include a reference on recommendations or guidelines on transitioning the patient. Mr. Monaghan stated he will research that and added that Dr. Marx has transitioned patients and it certainly can be done, for instance, by using fentanyl patches which has been successful.

MOTION: **Paul Oesterman motioned to accept the proposed criteria for Actiq® and Fentora® as presented. If there is claims submission after the effective date of the implementation of the new policy, the claim will process within the approval period of the PA process. Notification of the new policy will be sent to the prescribers of recipients currently on the medication.**
SECOND: **Marjorie Uhalde**
VOTES: **Unanimous**
MOTION CARRIED

V. Proposal by First Health Services to Adopt New Clinical Prior Authorization Criteria for Regranex® per Recent FDA Warning Updates

Jeff Monaghan stated that Regranex® is a topical formulation of recombinant human growth factor that is used for diabetic ulcers. The manufacturer, Ortho-McNeil, sent a letter to physicians regarding the safety issues surrounding Regranex®. The letter cited a study that indicated there was a five-fold increased risk of cancer mortality in a group that was exposed to three or more tubes of Regranex® gel hence the black box warning. Based on the black box warning, proposed PA criteria were presented which require a diagnosis of diabetic ulcer, age $\geq$16 years old and a quantity/refill limit of the original prescription (15 grams maximum/prescription) plus one refill (15 grams maximum/prescription) or a total life-time dose of 30 grams per patient.

Public Comment

No comment.

Discussion and Action by Board Concerning Revisions to Clinical Prior Authorization Criteria for Regranex®

MOTION: **Steven Parker motioned to accept the proposed criteria for Regranex® as presented.**
SECOND: **Paul Oesterman**
VOTES: **Unanimous**
MOTION CARRIED

VI. Nevada Medicaid Drug Utilization Review Annual Report Fiscal Year 2007

Presentation by First Health Services of the Nevada Medicaid Drug Utilization Review Annual Report Fiscal Year 2007

Jeff Monaghan presented an overview of the Nevada Medicaid Drug Utilization Review (DUR) Report for Federal Fiscal Year 2007. The annual report is a summarization of drug utilization review, outcomes, cost savings, number of prospective drug utilization alerts experienced, retrospective drug utilization review intervention statistics and DUR Board activity. The report is prepared by First Health and submitted to DHCFP for review, approval and submission to CMS. States are required by the federal government to submit this report annually.

During the reporting period, 3,600 patient profiles were reviewed for retrospective drug use review (RetroDUR). The clinical pharmacist reviewing the profiles identified 560 profiles to be

selected for a letter to be sent to the prescribers and/or pharmacies. The estimated annual costs savings from RetroDUR was $462,482.18. The drug spending curve remains flat to continuing to go down.

He reviewed the Population Analysis report which includes data for drug usage and overall cost for various age groups. The age group 40-65 comprises the largest group of program dollars. The major drug expenditures for this group were in the narcotic and tranquilizer agents.

The top thirty new drugs contributed $431,651 in new expenses (0.5% of the total drug spend) which is a decrease in dollars for new drug expenditures compared to FFY 2006.

Accomplishments in FFY 2007 include ProDUR and RetroDUR cost avoidance, a decrease in the average payment/user/month, generic substitution continues to increase, implementation of new clinical edits, and the educational program on "Psychotherapeutic Drug Therapy" provided to physician, nurses and pharmacists.

Initiatives planned for 2008 include, polypharmacy, antipsychotic utilization, streamlining PA requirements, narcotic utilization with the lock-in program, asthma management, tamper-resistant prescription pad requirements, NPI and e-prescribing.

Mr. England felt that one of the goals through the DUR Board could be to approach the medical associations and board of pharmacy to implement therapeutic substitution in the retail setting based on criteria established by the Board.

Ms. Lawrence stated that it is a federal requirement to provide this report. It's a statement on the accomplishments of the DUR Board. She would like the focus to be on this report and what the Board's charge is for next year. In terms of this report, if it's approved by the Board today, the final will include some formatting changes, 2004 references will be deleted and additional cost figures will be included. She recommended that future initiatives include a review of the age group 40-65 which comprise the largest group of program dollars (51.1%) as well as areas of focus recommended by the Board upon their review of the report. She added that antipsychotic utilization in children 0-12 years of age is increasing and DHCFP and First Health will be presenting proposed criteria at the next meeting.

Mr. Oesterman said that the section of the report on new products listed four products for diabetic patients that are combination products. He would like to see when the patents on the individual components expire.

Dr. Uhalde commented on therapeutic substitution. She recommended being the advocate for the patient by doing something similar to what drug manufacturers do. Drug companies send notifications to physicians with information regarding the cost of therapeutically equivalent drugs.

Discussion and Action by Board to Approve Nevada Medicaid Drug Utilization Review Annual Report Fiscal Year 2007

MOTION: Paul Oesterman motioned to approve the annual report as presented.
SECOND: Marjorie Uhalde
VOTES: Unanimous
MOTION CARRIED

VII. Presentation by First Health Services and Discussion by Board of Prospective Drug Utilization Review (Pro DUR) Reports

A. Top 50 Drugs Ranked by Payment Amount

B. Top 10 Therapeutic Classes by Payment Amount

C. Pro DUR Message Report

Jeff Monaghan presented drug utilization reports for second quarter 2008. He stated that there has not been a major shift within the top fifty drugs since the last report noting that the top seven high dollar drugs are psychotropic agents.

VIII. Presentation by First Health Services on Retrospective Drug Utilization Review Results

Jeff Monaghan presented the RetroDUR Summary Report for first quarter 2008. The current focus for RetroDUR is polypharmacy. Ms. Lawrence added that polypharmacy is a specific budget reduction measure for the State.

IX. Clarification of Board's Role Regarding the Consideration of Drug Cost - Darrell Faircloth, DAG

Darrell Faircloth addressed the issue regarding cost consideration by the Board when developing step therapy protocols as requested by Dr. Parker at the last meeting. State statute prohibits the DUR Board from utilizing the cost of prescription drugs when developing step therapy protocol. NRS 422.403.2(c) states: The Board shall "Review and approve, based on clinical evidence and best clinical practice guidelines and without consideration of the cost of the prescription drugs being considered, step therapy protocols used by the Medicaid program for prescription drugs."

X. Request by First Health Services for Clarification Regarding Lyrica® Motion From Last Board Meeting Minutes

Jeff Monaghan referred to the April 17, 2008, minutes. A motion was made to provide data on cost associated with pre-Lyrica® and post-Lyrica® usage and the impact in usage of other medications when the patient is placed on Lyrica®. At that time, Mr. Faircloth reminded the Board that cost cannot be considered and the Board in turn requested he report at today's meeting the Board's responsibility in terms of cost.

Mr. England stated that the Board's initial discussion at the last meeting did not address cost. Cost entered the discussion based on public comment.

Mr. Oesterman suggested presenting data on prescription volume.

Mr. England stated that he has personally never dispensed or seen Lyrica® used for epilepsy/seizure disorder. It does have its impact in diabetic peripheral neuropathy, post-herpetic neuralgia and fibromyalgia. He expressed concern when treating diabetic peripheral neuropathy, post-herpetic neuralgia which can occur in older patients 60 years of age and above. The Beers criteria indicate that tricyclic antidepressants aren't contraindicated but they are recommended to be used sparingly or not at all in that age group because of the side effect profile and as well as an increased risk in falls. The edit requires a trial of tricyclic antidepressants or gabapentin before Lyrica® is authorized. He felt this needs to be considered when setting up the edit.

Mr. Wuest responded that the concern is valid but with this age group, the majority of the patients are covered by Medicare Part D and Medicaid is secondary covering only the co-pay in most cases. These criteria would not apply to the Part D recipients.

Dr. Parker asked if it's known if the medication is being used for approved indications. Mr. Monaghan replied no. Ms. Lawrence said that the proposed PA criteria states use of this drug is for proper indications and indication of this drug depended on the process that the practitioner would go through. It wasn't a matter of cost but proper utilization. There may be an impact on cost but it doesn't take away from making appropriate decisions to the clinical measures on it.

She suggested reviewing the three indications outlined in the proposed criteria and consider if this is the clinical pathway the Board wants to see the utilization for this indication. If there are other circumstances such as age or use of other medications to be considered, open that discussion at the next meeting. Mr. Monaghan supported Ms. Lawrence's comments adding that utilization data can be presented but the issue is the correct clinical pathway.

Dr. Parker commented that a review of the data will give a better idea in developing the appropriate clinical pathway and requested that both be presented at the next meeting.

Motion by Board to Provide Data Regarding Lyrica® Utilization

Deferred until next meeting.

XI. Public Comment

Mike Steelman, Pfizer, spoke in support of Celebrex®. He requested the Board review the Cox-2 PA. Celebrex® has an indication for juvenile rheumatoid arthritis which is not listed in the criteria. The criteria states, "Patient is currently NOT being treated daily with aspirin for cardio-prophylaxis." Celebrex® can be used with low-dose aspirin.

XII. Date and Location of Next Meeting

The next meeting is scheduled for October 23, 2008.

XIII. Adjourn

MOTION: Paul Oesterman motioned to adjourn the meeting.
SECOND: Steven Parker
VOTES: Unanimous
MOTION CARRIED
Meeting adjourned at 2:19 p.m.